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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,543	11/21/2000	Fenyong Liu	BERK-005	2657

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/31/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/721,543	LIU ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8,10,12-16,19,21,23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 8, 10, 12-16, 19, 21, 23 and 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' amendment filed on 10/22/02 in Paper No. 12 has been entered in part. The amendments to the specification have not been entered because they do not comply with 37 CFR 1.121. No clean version of the amendments to the specification has been submitted.

Applicants in their remarks appear to be arguing the restriction requirement (see pages 4-5 of the Amendment). However, the restriction requirement has been made FINAL in the previous Office Action mailed on 6/19/02 in Paper No. 9, and therefore further arguments will not be entertained.

Amended claims 1, 6, 8, 10, 12-16, 19, 21, 23 and 25-26 are pending in the present application.

The text of those sections of Title 35 U.S.C. Code not included in this action can be found in a prior Office Action.

Response to Amendment

The rejection under 35 U.S.C. 102(b) as being anticipated by Pan et al. (Proc. Natl. Acad. Sci. U.S.A. 92: 11509-11513, 1995) is withdrawn in view of Applicants' amendment.

The rejection under 35 U.S.C. 102(b) as being anticipated by Ecker et al. (U.S. Patent No. 5,523,389) is withdrawn in view of Applicants' amendment.

The rejection under 35 U.S.C. 102(b) as being anticipated by Wang et al. (U.S. Patent No. 5,856,085 with the effective filing date of 12/1/1995) is withdrawn in view of Applicants' amendment.

Following is a new ground of rejection necessitated by Applicants' amendment.

Written Description

Amended claims 1, 6, 12-16 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

Applicant's invention is drawn to an anti-human cytomegalovirus RNAase resistant RNA polynucleotide ligand composition of from 15 to 100 nucleotides in length, wherein the RNA polynucelotide ligand lacks complementary to a human

cytomegalovirus genetic sequence, and wherein it binds to a human cytomegalovirus and inhibits human cytomegalovirus infection. Applicants' invention is also drawn to a method of treating human cytomegalovirus infection comprising administering an effective dose of the same anti-human cytomegalovirus RNAase resistant RNA polynucleotide ligand composition into a patient in need thereof to decrease human cytomegalovirus infection. The instant claims encompass any anti-human cytomegalovirus RNAase resistant RNA polynucleotide composition of from 15 to 100 nucleotides in length (4^{15} to 4^{100} RNA polynucleotide ligand species) that binds to a human cytomegalovirus via any envelope or any capsid protein to inhibit human cyomegalovirus infection (an antiviral activity); and a method of treating human cytomegalovirus infection using the same composition. In analyzing whether the required written description is met for genus claims, it is first determined whether a representative number of species has been described by their complete structure. Apart from disclosing 3 distinct RNA polynucleotide ligands L13, L19 and L66 (SEQ ID NOs 2, 12 and 36, respectively; L13 and L66 belong to the non-elected groups of sequences) selected from various distinct groups of RNA ligand sequences listed in Tables 1 & 2, that are capable of blocking human cytomegalovirus (hCMV) entry into targeted cell via their specific binding to hCMV envelope glycoproteins gH, gB and gB, respectively, the instant specification fails to disclose a representative number of RNA polynucleotide ligands that have hCMV antiviral activity via the binding of any hCMV envelope or capsid proteins, particularly for a genus of elected RNA polynucleotide ligands of from 15 to 100 nucleotides in length that share sequence similarity or

common core structures to any of SEQ ID NO:12-16. It is further noted that there is no apparent correlation between the ability of an RNA polynucleotide ligand to bind to hCMV and its ability to block hCMV entry into a cell as evidenced by the teachings of the present application for the ligands L17 and L31 (see examples 1 and 2 of the instant specification). Apart from the common functional limitation of binding to a human cytomegalovirus and inhibiting human cytomegalovirus infection, the specification fails to disclose or identify the relevant structural characteristics or common essential core elements for a representative number of RNA polynucleotide ligand species possessing the desired anti-human cytomegalovirus activity, and that they are related to the elected group of SEQ ID NO:12-16. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants' filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). With respect to the elected invention, the skilled artisan cannot envision the detailed structure of a representative number of species having the anti-human cytomegalovirus activity other than L19 (SEQ ID NO:12) and a method for decreasing human cytomegalovirus infection using a broadly claimed anti-human cytomegalovirus RNAase resistant RNA polynucleotide composition, and therefore conception is not achieved until reduction to practice has occurred, regardless of the

complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Amended claims 1, 6, 8, 12-16, 21 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, with respect to the elected invention while being enabling for an anti-human cytomegalovirus RNAase resistant RNA polynucleotide ligand composition comprising the polynucleotide sequence set forth in SEQ ID NO:12 and a method of treating human cytomegalovirus infection in a patient, said method comprising administering into said patient an anti-human cytomegalovirus RNAase resistant RNA polynucleotide ligand composition comprising the polynucleotide sequence set forth in SEQ ID NO:12 at a dose sufficient to decrease cytomegalovirus infection, and thereby treating human cytomegalovirus infection in said patient, does not reasonably provide enablement for any anti-human cytomegalovirus RNAase resistant RNA polynucleotide composition of from 15 to 100 nucleotides in length and which lacks complementarity to the human cytomegalovirus, and a method of treating human cytomegalovirus infection using the same. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The instant claims encompass any anti-human cytomegalovirus RNAase resistant RNA polynucleotide composition of from 15 to 100 nucleotides in length (4^{15} to 4^{100} RNA polynucleotide ligand species) that binds to a human cytomegalovirus via any envelope or any capsid protein to inhibit human cyomegalovirus infection (an antiviral activity) and a method of treating human cytomegalovirus infection using the same composition. With respect to the elected invention, the instant specification is not enabled for such a broadly claimed invention because in light of the fact that Applicants were not in full possession of a representative number of species of anti-human cytomegalovirus RNA polynucleotide within a broad genus of the elected group of RNA ligand sequences, coupled with the lack of sufficient guidance provided by the prior art at the effective filing date of the present application on this matter, it would have required undue experimentation for a skilled artisan to make and use the instant broadly claimed invention.

With respect to claims 8 and 21 specifically encompassing polynucleotide ligands comprising sequences of SEQ ID NOs. 14-16 having anti-human cytomegalovirus activity, the instant specification is not enabled for such a claimed invention. This is no evidence of record indicating that polynucleotide ligands having SEQ ID NOs. 14-16 possess any antiviral activity. Although L49 (SEQ ID NO. 16) has extensive homology with L11 (SEQ ID NO. 14) and L58 (SEQ ID NO. 15), and that all of the RNA ligands can bind to hCMV viral particles, it is unclear whether these ligands are also capable of blocking hCMV entry into a cell by binding to any of its envelope or capsid glycoproteins. Moreover, there is no apparent correlation between the ability of an RNA polynucleotide ligand to bind to hCMV and its ability to block hCMV entry into a cell as evidenced by the teachings of the present application for the ligands L17 and L31 (see examples 1 and 2 of the instant specification). Among the elected group of RNA polynucleotide ligands, SEQ ID NO:12 is the sole RNA ligand that is capable of blocking human cytomegalovirus (hCMV) entry into targeted cell via its specific binding to hCMV gB envelope glycoprotein. However, the instant specification fails to teach or identify the critical features or core structures possessed by SEQ ID NO:12 that are responsible for its anti-human cytomegalovirus activity, so that a skilled artisan in the art could recognize whether SEQ ID NOs: 14-16 or any RNA ligand species within the elected group of sequences also possess the same critical features or core structures essential for the desired anti-human cytomegalovirus activity. It is apparent that such anti-human cytomegalovirus activity has to be determined empirically, and that there is no way to predict which nucleotide modification (addition, deletion, substitution) at which

nucleotide position and in which combinations with respect to SEQ ID NO:12, such that one skilled in the art would obtain RNA ligand variants possessing anti-human cytomegalovirus activity.

Furthermore, the physiological art is recognized as unpredictable (MPEP 2164.03). As set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> That scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the are; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

Additionally, with respect to the breadth of the instant claims, Applicants' attention is further directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

The courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel.*).

Accordingly, due to the lack of guidance provided by the specification regarding to the issues set forth above, the unpredictability of the physiological art and the breadth

of the claims, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

Responses to Arguments

Applicants' arguments related to the rejections on the lack of Written Description and Enablement in the Amendment filed on 10/22/02 in Paper No. 12 (pages 5-8) have been fully considered.

Applicants argue basically that the specification discloses guidance how to select for polynucleotides having specific binding to human cytomegalovirus, and how to determine whether such polynucleotides suppress or inhibit hCMC infection. Applicants also argue that although further experiments are required to determine the presence of anti-human cytomegalovirus activity for a broadly claimed RNA polynucleotide ligand composition of the presently claimed invention and that these experiments are empirical in nature, but they are routine and therefore no undue experimentation was required. Additionally, Applicants argue that the specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art would be able to practice the invention without undue experimentation, and that the skill level of an ordinary skilled artisan in the field of the presently claimed invention is high. Applicants further argue that even in unpredictable arts, the specification does not have to disclose every species of a genus that would work and every species that would not work, and that the instant claims exclude RNA polynucleotide ligands that do not inhibits

human cytomegalovirus infection. Applicants' arguments are respectfully found to be unpersuasive for the following reasons.

Firstly, with respect to the lack of Written Description, *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). Additionally, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. Within the elected invention, apart from disclosing SEQ ID NO:12 is the sole RNA ligand that is capable of blocking human cytomegalovirus (hCMV) entry into targeted cell via its specific binding to hCMV gB envelope glycoprotein, the instant specification fails to disclose or identify the relevant structural characteristics or common essential core elements for a representative number of RNA polynucleotide ligand species (within a genus containing 4^{15} to 4^{100} RNA polynucleotide ligand species) possessing the desired anti-human cytomegalovirus activity, and that these RNA ligands are related to the elected group of SEQ ID NO:12-16. As Applicants also admit that experiments that are required to determine whether the RNA polynucleotide ligands possessing anti-human cytomegalovirus activity are empirical in nature, indicating or suggesting that it is unpredictable to know which RNA polynucleotide ligands would or would not possess the desired anti-human cytomegalovirus activity. Therefore, apart from the RNA polynucleotide ligand composition comprising SEQ ID NO:12, the specification fails to

provide adequate description for a representative number of species RNA polynucleotide ligands that are related to SEQ ID NO:12, and that they exhibit anti-human cytomegalovirus activity. What are the sequences (necessary for a proper 3-dimensional folding or by other means) that these RNA ligands need to possess in order for them to exhibit anti-human cytomegalovirus activity? It is further noted that merely binding to a human cytomegalovirus does not necessarily lead to the inhibition or decrease human cytomegalovirus infection as evidenced by the teachings of the present application for the ligands L17 and L31 (see examples 1 and 2 of the instant specification). As such, at the effective filing date of the present application, Applicants have not in full possession for a representative number of species of anti-human cytomegalovirus RNA polynucleotide ligand within a broad genus of elected group of RNA ligand sequences.

Secondly, with respect to the Enablement rejection, in light of the fact that at the effective filing date of the present application, Applicants were not in full possession of a representative number of species of anti-human cytomegalovirus RNA polynucleotide ligand within a broad genus of elected group of RNA ligand sequences as discussed in the preceding paragraphs, and since the prior art does not teach or provide any guidance on this regard, then it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention. In order for one skilled artisan to make and use the full scope of the presently claimed invention, further experimentation is required, and that the nature of the required further experimentation is empirical (also admitted by Applicants), indicating or suggesting that that it is

unpredictable to know which RNA polynucleotide ligands would or would not possess the desired anti-human cytomegalovirus activity. With respect to the breadth of the instant claims encompassing a broad genus containing 4^{15} to 4^{100} RNA polynucleotide ligand species having anti-human cytomegalovirus activity, and given the unpredictability of knowing which RNA ligands would or would not posses the desired biological activity, and simply based on the disclosure of the RNA ligand having SEQ ID NO:12 for the elected invention, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention. Furthermore, with regard to the breadth of the instant claims, Applicants' attention is further directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

Additionally, the courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel.*).

Examiner would like to further note that should Applicants continue to argue that it is routine and does not require an ordinary skilled artisan to determine RNA ligands having anti-human cytomegalovirus activity, then Applicants in effect also argue the teachings of Wang et al. (U.S. Patent No. 5,856,085; cited previously) is enabled for the presently claimed invention. This is because although Wang et al. do not teach or

disclose any specific RNA sequences having anti-human cytomegalovirus activity, Wang et al. do teach the same method for identifying single-stranded nucleic acid molecules (including RNA and RNA analogs) which inhibit infection by infectious agents that include cytomegalovirus among other infectious viruses, and based on Applicants' arguments and the teachings of Wang et al., it would not have required any undue experimentation for one skilled in the art to arrive at the instantly claimed invention.

For the reasons discussed above, amended claims 1, 6, 12-16 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, for the lack of Written Description; and amended claims 1, 6, 8, 12-16, 21 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, for fully enabled the instant broadly claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8, 10, 12-16, 19, 21, 20, 23 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15 and their dependent claims recite the limitation "said human cytomegalovirus genetic sequence". There is insufficient antecedent basis for this limitation in the claim. This is because there is no previous recitation of any human cytomegalovirus genetic sequence in claims 1 and 15.

Claims 19, 23 and 26 are dependent on the cancelled claims 18 and 20. Therefore, the metes and bounds of these claims are not clearly determined because it is unclear what exactly Applicants intend to claim.

Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (703) 308-1906, or SPE, Remy Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to LIE, Tiffiany Tabb, whose telephone number is (703) 605-1238.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER